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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,637	04/30/2001	Michael C. Jensen	24751-2502	4845

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EXAMINER

CHEN, LIPING

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/05/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,637

Applicant(s)

JENSEN, MICHAEL C.

Examiner

Liping Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-165 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-165 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- ☐ Interview Summary (PTO-413) Paper No(s). ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to an isolated human IMPDH protein that contains one or more alterations, classified in 435, subclass 183⁺.
- II. Claims 7-22, drawn to an isolated nucleic acid encoding IMPDH that contains one or more alterations, a vector or a cell, classified in 514, subclass 44.
- III. Claims 23-54, 63, 65-82, 85, and 141-143, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered human IMPDH is introduced in to the first cell *in vitro*, classified in 514, subclass 44.
- IV. Claims 23-53, 55, 56, 59, 60, and 63-82, 85, and 141-143, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered human IMPDH is introduced in to the first cell *in vivo*, classified in 514, subclass 44.
- V. Claims 23-53, 57, 58, 61-82, 85, and 141-143, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered human IMPDH is introduced in to the first cell *ex vivo*, classified in 424, subclass 93.21.
- VI. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered ribose phosphate pyrophosphokinase is introduced in to the first cell, classified in 514, subclass 44.
- VII. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered

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amidophosphoribosyltransferase is introduced in to the first cell, classified in 514, subclass 44.

VIII. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered glycnamide ribonucleotide (GAR) synthetase is introduced in to the first cell, classified in 514, subclass 44.

IX. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered GAR transformylase is introduced in to the first cell, classified in 514, subclass 44.

X. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered formylglycinamidine ribonucleotide synthetase is introduced in to the first cell, classified in 514, subclass 44.

XI. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered aminoimidazole ribonucleotide (AIR) synthetase is introduced in to the first cell, classified in 514, subclass 44.

XII. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered AIR carboxylase is introduced in to the first cell, classified in 514, subclass 44.

XIII. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered aminoimidazolesuccinocarboxamide ribonucleotide synthetase is introduced in to the first cell, classified in 514, subclass 44.

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- XIV. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered adenylosuccinate synthase is introduced in to the first cell, classified in 514, subclass 44.
- XV. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered adenylosuccinate lyase is introduced in to the first cell, classified in 514, subclass 44.
- XVI. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered aminoimidazolecarboxamide ribonucleotide (AICAR) transformylase is introduced in to the first cell, classified in 514, subclass 44.
- XVII. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered inosine monophosphate (IMP) cyclohydrolase is introduced in to the first cell, classified in 514, subclass 44.
- XVIII. Claims 23-32, 83 and 84, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered GMP synthase is introduced in to the first cell, classified in 514, subclass 44.
- XIX. Claims 23-31, 86-99, 108, 110-117, and 144, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered mammalian dihydroorotate dehydrogenase (DHODH) is introduced into the first cell *in vitro*, classified in 514, subclass 44.
- XX. Claims 23-31, 86-98, 100, 101, 104, 105, 108-117, and 144, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered mammalian dihydroorotate dehydrogenase (DHODH) is introduced into the first cell *in vivo*, classified in 514, subclass 44.

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XXI. Claims 23-31, 86-98, 102, 103, 106, 107-117, and 144, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding an altered mammalian dihydroorotate dehydrogenase (DHODH) is introduced into the first cell *ex vivo*, classified in 424, subclass 93.21.

XXII. Claims 118-129, 130, 132-134, 155-159, drawn to a method of providing for selective proliferation of first cell relative to a second cell *in vivo*, where the altered nucleic acid is introduced to first cell *in vivo*, classified in 514, subclass 44.

XXIII. Claims 118-129, 131, 135, 136, and 155-157, drawn to a method of providing for selective proliferation of first cell relative to a second cell *in vivo*, where the altered nucleic acid is introduced to first cell *ex vivo*, classified in 424, subclass 93.21.

XXIV. Claims 137, 139, 145-154, drawn to a method of providing for selective proliferation of first cell relative to a second cell in an organism, where the heterologous nucleic acid is introduced into first cell *in vivo* with a marker nucleic acid, classified in 514, subclass 44.

XXV. Claims 138 and 140, drawn to a method of providing for selective proliferation of first cell relative to a second cell in an organism, where the heterologous nucleic acid is introduced into first cell *ex vivo* with a marker nucleic acid, classified in 424, subclass 93.21.

XXVI. Claims 160-165, drawn to a method of providing for selective proliferation of first cell relative to a second cell, where the nucleic acid encoding a non-altered IMPDH is introduced into the first *in vitro* and IMPDH is from a species other than a mammalian species, classified in 514, subclass 44.

Note: 1) Claims 85 and 97 are lacking of antecedent basis. Applicant is advised to correct the dependency of both claims.

2) Claims 150-154 are the duplicates of claims 145-149. Should applicant change claim 150 depending on claim 138, claims 150-154 will be grouped into Group XXV.

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- 3) Claim 159 is a duplicate claim of 158. Should applicant change claim 159 depending on claim 131, claim 159 will be grouped into Group XXIII.

The inventions are distinct, each from the other because:

Inventions I and II are two distinct products. The protein of invention I can be used to produce antibody. The nucleic acid of invention II can be used for nucleic acid hybridization assay.

Invention I and any one of inventions III-XXVI are mutually exclusive and independent. The isolated protein of invention I is not needed for the implementation of methods of any of the invention

III-XXVI, and vice versa. Each of the methods requires a separate and materially different protocol.

Inventions II and III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of invention II can be used for nucleic acid hybridization assays.

Invention II and any one of inventions VI-XXVI are mutually exclusive and independent. The isolated nucleic acid of invention II is not needed for the implementation of methods of any of the invention VI-XXVI, and vice versa. Each of the methods requires a separate and materially different protocol.

Inventions III-XXVI are distinct each from the other because each group is either contains a different enzyme or requires different technical to introduce the nucleic acid to the first cell (such as *in vitro*, *in vivo*, or *ex vivo*), or under different condition to compare with the second cell (*in vitro* or *in vivo*), or containing second nucleic acid for introducing to the first cell. The technique used for each group is different with other groups. Therefore the search required for any group is not required for all others. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is

elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

As indicated above, applicant is required to elect one group for restriction practice. Should applicant choose to do so, any sequences fully embedded in the elected sequence will also be examined. Applicant is required to identify any such embedded sequences and there cannot be any overlap with other sequences not in the elected sequence.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632
May 10, 2002

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630